

Application No. 10/007,733
Reply dated 16 July 2004
Responsive to Office Action mailed on 7 June 2004

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REMARKS**Amendment to the Description**

A U.S. Patent number has been substituted for the serial number of the corresponding U.S. Patent Application.

Amendments to the Claims

Claim 1 has been amended to incorporate the limitations formerly recited in dependent **Claim 2** and **3**, which have been cancelled.

Claim 9 has been amended to use language that is more consistent with the description of a step in a method by describing "using a bladder monitor to obtain the objective measurement" of **Claim 1**.

Claim 10 has been amended to use language that is more consistent with the description of a step in a method by describing "utilizing ultrasound to obtain the objective measurement" of **Claim 1**.

Claim 11 has been amended to use language that is more consistent with the description of a step in a method by describing "applying a bladder monitor to the child's body in a wearable manner and using the bladder monitor to obtain the objective measurement" of **Claim 1**.

Claim 12 has been amended to incorporate the limitations formerly recited in dependent **Claim 13** and **14**, which have been cancelled.

Claim 18 has been amended similarly to **Claim 9**.

Claim 19 has been amended similarly to **Claim 11**.

Claim 20 has been amended to include the limitations formerly recited in other claims, including in **Claims 2, 3, 13, and 14**.

Objection to the Drawings

The Office Action contained an objection to the drawings on the basis that "[t]he drawings must show every feature of the invention specified in the claims. Therefore, each of the (i) "bladder monitor", (ii) wearable bladder monitor", (iii) means for providing "an audible alarm, a tactile alarm, or a visible alarm", and (iv) "package", must be shown or the features canceled from the claim(s)." This objection is respectfully traversed and its reconsideration and withdrawal is requested in light of the following points.

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The text quoted above is part of form paragraph 6.36, the first sentence of which is derived from the first sentence of 37 CFR 1.83(a). Both the Rule and the form paragraph are recited in MPEP 608.02(d). Between the two in this section of the MPEP, it is recited that "[a]ny structural detail that is of sufficient importance to be described should be shown in the drawing. (*Ex part Good*, 1911 C.D. 43, 164 O.G. 739 (Comm'r Pat. 1911).)" (Underlining added for emphasis.) Thus, the context of the first sentence of 37 CFR 1.83(a) is that of claims to structures. In fact, the objection itself refers to four enumerated structures and/or physical objects. However, every one but one of the present claims is directed to a method rather than to a structure or a physical object.

In addition, each of the four items enumerated in the objection is conventional and its detailed illustration would not be essential for a proper understanding of the present invention, even if the claims were directed to the enumerated structures and/or physical objects, rather than being directed to methods. According to the second sentence of 37 CFR 1.83(a), such "conventional features...where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated...in the form of a...labeled representation (e.g., a labeled rectangular box)." Thus, even if the fact that the claims are directed to methods, rather than to structures, were overlooked, each of the enumerated items would be shown merely as a rectangular box. It is respectfully submitted that additional drawings, each showing nothing more than a rectangular box, would not enhance the understanding of the claimed invention by one of skill in the art.

Only Claim 20 is directed to a physical object, namely a simple article of commerce comprising a package containing a bladder monitor and instructions. Thus, a drawing corresponding to Claim 20 would contain nothing more than two small rectangular boxes contained within another rectangular box and, again, such a depiction would not enhance the understanding of the claimed invention by one of skill in the art.

Furthermore, the enumeration of the four items lends more weight than is appropriate to the notion that additional drawings are necessary for the comprehension of the invention. For instance, the use of the adjective "wearable" in the term "wearable bladder monitor" in Claims 11 and 19 prior to their present amendment would not necessitate a separate drawing element in addition to a rectangular box representing a bladder monitor in general. Also, nowhere in the claims is a "means for providing an audible alarm, a tactile alarm, or a visible alarm" recited; instead, in Claim 8, the signal is described as being an audible alarm, a tactile alarm, or a visible alarm. Thus, the term "alarm" is clearly used in the sense of "a signal (as a loud noise or flashing light) that warns or alerts" (Merriam-Webster OnLine

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dictionary at <http://www.m-w.com/home.htm>), and it is not clear how a signal by itself would be shown on a drawing.

Therefore, it is respectfully averred that no additional drawings are needed for one of skill in the art to comprehend the present invention. It is respectfully requested that the objection to the drawings be reconsidered and withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Claims 1 through 20 were rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 4,852,578 to Companion *et al.* Claim 2, 3, 13, and 14 have been cancelled, thereby obviating their rejection and leaving Claims 1, 4 through 12, and 15 through 20 pending and rejected.

Independent Claims 1, 12, and 20 have been amended to incorporate the limitations previously recited in dependent Claim 2, 3, 13, and 14, namely the steps of measuring the reflexive urination volume of the child being continence trained and setting the signal threshold value to correspond to a bladder volume that is less than the reflexive urination volume. All of the other pending claims depend from and therefore contain all the limitations of these three independent claims. Therefore, it is respectfully averred that the requirements of MPEP 2143 for the establishment of a *prima facie* case of obviousness have not been met with respect to any of the rejected claims.

Omission of reflexive urination volume

The term "reflexive urination volume" is clearly defined in the specification as originally filed, including in the paragraph beginning on page 3 at line 31. In this paragraph, the term "reflexive" is explicitly defined as referring to "an action of the nervous system, below the level of consciousness, in which a muscular response to a stimulus is automatically effectuated." Exemplary methods for determining the reflexive urination volume are clearly described in the paragraph beginning on page 4 at line 9, *i.e.*, in the paragraph immediately following the paragraph in which the term is defined. These exemplary methods are suitable for measuring the volume of urine that is discharged by reflex action, that is, by an automatic action of the nervous system below the level of consciousness.

On the other hand, the cited Companion *et al.* reference fails to disclose a reflexive urination volume, any measurement of a reflexive urination volume, or any setting of a signal threshold value to correspond to a bladder volume that is less than a reflexive urination volume. Instead, the reference repeatedly emphasizes conscious perception and the making of a conscious decision to either urinate or delay urination, rather than reflex action. For example, the reference repeatedly refers, with slight variation, to

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helping a human subject "recognize the preliminary need to urinate" (2:11-12; 2:16-17; 2:54-55; 2:67-68; note that line numbers are printed between the lines in the patent, making exact identification difficult). Recognition clearly requires conscious perception. Similarly, in the paragraph beginning in column 7 at line 49, the reference describes the subject as "want[ing] to accumulate an appreciable volume of urine in the bladder before taking the time to void" (7:51-53), being able to "choose to void at this time", or "not...[choosing]...to void at the first sensation" (7:61-63). Conscious perception is clearly required in order to perform every one of the activities mentioned, namely wanting, *i.e.*, desiring, to accumulate urine, taking time to urinate, choosing to void, or choosing not to void.

As mentioned in the Office Action, the reference mentions an "intermediate alarm level" in the same paragraph beginning in column 7 at line 49. However, this mention occurs in a specific context, which is that of finding a setting that does "not produce any false alarms" (7:57-57) and thereby results in "eliminating false positives" (8:1-2). The following portions of this paragraph are quoted here to ensure that the proper context is conveyed:

Since it is reasonable to assume that the individual will want to accumulate an appreciable volume of urine in the bladder before taking the time to void, an intermediate alarm level was selected for the test program. It was noted that when the bladder is empty, or when it has a very small amount of urine therein, body movement did not produce any false alarms...The individual, or the individual's caretaker can over a period of time adjust the alarm level to that point which works best for the individual involved eliminating false positives for certain individual [*sic*].

Thus, the entire paragraph beginning in column 7 at line 49 deals with avoiding "false alarms" for a subject who is clearly described as consciously perceiving various stimuli and consciously deciding to either act or not act in response to those stimuli.

The Office Action also refers to the disclosure in the cited reference that various alarm levels may be selected. However, the mere disclosure that various levels may be selected does not constitute any hint or suggestion to measure a reflexive urination volume and select an alarm level corresponding to a bladder volume that is less than that measured reflexive urination volume. Also, it is not clear from the reference whether or not the disclosed range even includes a typical child's reflexive urination volume. In fact, the anatomical differences between children and adults is repeatedly emphasized in the cited reference, including at 4:9-10, 4:60-62, and 6:50-51, and it is explicitly disclosed at 6:55-56 that the test population from which its disclosure was derived was one of adult males, *i.e.*, a class of humans who are explicitly described as being significantly different from children in the very portions of the anatomy that

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affect urination, the measurement of bladder volume, and continence. Furthermore, even if the disclosed range of alarm levels includes a level that could be a particular child's reflexive urination volume, there is no suggestion or motivation provided by the cited reference to select an alarm level based on a measurement of a reflexive urination volume.

Therefore, the statement in the Office Action that "Companion et al teaches setting the "signal"/alarm threshold value to correspond to a bladder volume that is "less than a reflexive urination volume"" is not supported by the disclosure of the reference and so appears to be merely an allegation that such a value could be selected for the alarm level of the cited reference. However, as clearly stated in MPEP 2143.01, the mere fact that a reference could have been modified, or that the level of skill in the art may have been adequate to modify it, is insufficient to establish a *prima facie* case of obviousness. In addition, given the utter lack of expression in the cited reference of a recognition of the usefulness of selecting an alarm level in relation to a measured reflexive urination volume, a statement implying that it would have been obvious to do so can be based only on either conjecture or the application of impermissible hindsight in light of the disclosure of the present invention.

Alternatively, the statement in the Office Action that is quoted above could be taken to be an allegation that the selection of a signal threshold value to correspond to a bladder volume that is less than a reflexive urination volume is inherent in the disclosure of the cited reference. However, as is clearly stated in MPEP 2112, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic" and that the burden is on the Examiner to show "that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." It is respectfully averred that this burden has not been met.

In summary with regard to the reflexive urination volume, nowhere in the cited reference is there any mention of a measurement of a reflexive urination volume or the setting of a signal threshold value to correspond to a bladder volume that is less than a measured reflexive urination volume. In fact, a complete reading of the reference without recourse to the subject Application would lead one of skill in the art to conclude that Companion *et al.* failed to appreciate the usefulness of a measurement of the reflexive urination volume in determining an appropriate signal threshold value.

Therefore, it has not been demonstrated that the cited prior art reference teaches or suggests all of the limitations of the rejected claims or that any suggestion or motivation exists, other than in the present inventor's own disclosure, to modify the reference's teachings to make the present invention. Thus, at

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least two of the three requirements of MPEP 2143 for the establishment of a *prima facie* case of obviousness have not been met with respect to any of the rejected claims.

Additional points

The following additional points in the Office Action also bear notice and further confirm the insufficiency of the Office Action to establish a *prima facie* case of obviousness.

The disclosure of the cited reference is mischaracterized in the Office action where it is stated that "the system "recogniz(es) the preliminary need (of the subject) to urinate"". The actual text in column 2, last paragraphs, reads that a "further object of this invention is...providing vital information needed by the subject...and affording help to the subject in recognizing the preliminary need to urinate." The system does not "recognize" the need to urinate; it merely provides information to help the human subject who recognizes the need.

The disclosure of the cited reference is mischaracterized in the Office action where it is stated that "the system of Companion et al "trains" a human subject to "achieve urinary continence". The system merely provides information, as noted immediately above; the human user of the system trains the subject.

The disclosure of the cited reference is mischaracterized in the Office action where it is stated that "Companion et al characterizes the disclosed system as a "complete electronics package" which is "worn by the subject", i.e. the system is a self-contained "monitor"; it would have been obvious to those skilled in the art that, for commercial purposes, the self-contained electronics device of Companion et al may be "package(d) [sic]" with "instructions" for using the device, in order to enhance the marketability and convenience of the device to consumers." First, the usage of the word "package" in the cited reference is distinctly different from its usage in Claim 20. An "electronics package" means a system of electronic devices that can function without external connections, i.e., the "self-contained" system. This meaning has nothing to do with the meaning of a package for sale, as in the article of commerce of Claim 20, which is well-known to be a container inside which goods are held for sale. In addition, the disclosure that the electronic system of the reference can be self-contained reveals nothing regarding whether or not a container in which it might be sold might contain instructions.

Furthermore, the above-quoted statement that it would have been obvious to include instructions appears to be another allegation that the teachings of the reference could be modified. However, as clearly stated in MPEP 2143.01, the mere fact that a reference could have been modified, or that the level of skill in the art may have been adequate to modify it, is insufficient to establish a *prima facie* case of obviousness. In

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addition, given the utter lack of expression in the cited reference of a recognition of the usefulness of selecting an alarm level in relation to a measured reflexive urination volume, a statement implying that it would have been obvious to include instructions to do so can be based only on either conjecture or the application of impermissible hindsight in light of the disclosure of the present invention.

The disclosure of the cited reference is mischaracterized in the Office action where it is stated that "Figs. 4a-c of Companion et al demonstrates a measurement of the bladder at "maximum fullness", i.e. the "reflexive urination volume". There is no mention of a reflexive urination volume in the reference. Therefore, the equation of "maximum fullness" with "reflexive urination volume" is an unfounded conjecture. Furthermore, that conjecture is contradicted by the explicit disclosure in the reference itself at 7:19-29 that "volumes in excess of 500 cc" were measured but that the members of "the test population...tended to void between...volumes of 240-260 cc...and...volumes of approximately 400 cc", i.e., at volumes of at least 20% less than the 500 cc volume observed at "maximum fullness". In fact, this conjecture belies the novelty of the present invention. Markedly unlike what is described by the conjecture that "maximum fullness" equals "reflexive urination volume", the present invention requires that a person practicing the claimed methods measure the reflexive urination volume of the subject and set the signal threshold such that the signal will be provided at a volume less than the measured reflexive urination volume, rather than arbitrarily (and illogically) setting the signal threshold such that the signal would be provided at the greatest volume that can be held by the bladder of the subject. It is noted that the condition of "maximum fullness", by the plain meaning of the term "maximum", is the condition of the greatest volume.

Summary with respect to obviousness rejections

In summary, it is respectfully averred that the requirements of MPEP 2143 for the establishment of a *prima facie* case of obviousness have not been met, for at least the reasons explained above. Accordingly, it is respectfully requested that the rejections of Claims 1, 4 through 12, and 15 through 20 under 35 USC § 103(a) be reconsidered in accordance with the requirements of MPEP 2142, last two paragraphs, and MPEP 2144.08.III, and then withdrawn.

Summary of this Response

No new matter has been added in this response. In light of the above amendments and remarks, it is respectfully requested that the rejections and objection be reconsidered and withdrawn and that the pending claims be allowed.

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